IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PF PRISM C.V., C.P. PHARMACEUTICALS INTERNATIONAL C.V., PFIZER PHARMACEUTICALS LLC, and PFIZER PFE IRELAND PHARMACEUTICALS HOLDING 1 B.V.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 17-158 (LPS) CONSOLIDATED
PRINSTON PHARMACEUTICAL INC.,	)	
Defendant.	)	

AMENDED COMPLAINT

Pfizer Inc., PF PRISM C.V., C.P. Pharmaceuticals International C.V., Pfizer Pharmaceuticals LLC, and Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. (collectively "Plaintiffs" or "Pfizer"), for their Amended Complaint against Defendant Prinston Pharmaceutical Inc., ("Prinston"), allege as follows:

NATURE OF THE ACTION

1. This is an action by Pfizer against Prinston for infringement of United States Patent No. 6,965,027 (the "'027 patent") and United States Patent No. 7,301,023 (the "'023 patent").

2. This action arises out of Prinston Pharmaceutical Inc.'s filing of Abbreviated New Drug Application ("ANDA") No. 209923 seeking approval by the United States Food and Drug Administration ("FDA") to sell generic copies of Pfizer's Xeljanz® prior to the expiration of the '027 and '023 patents.

THE PARTIES

3. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017.

4. Plaintiff PF PRISM C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. Pfizer Inc. is the ultimate parent company of PF PRISM C.V.

5. Plaintiff C.P. Pharmaceuticals International C.V. is a limited partnership (*commanditaire vennootschap*) organized under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017. Pfizer Inc. is the ultimate parent company of C.P. Pharmaceuticals International C.V.

6. Plaintiff Pfizer Pharmaceuticals LLC is a limited liability company organized and existing under the laws of Delaware and having its principal place of business at Bo. Carmelitas, Road 689, Km. 1.9, Vega Baja, Puerto Rico. Pfizer Inc. is the ultimate parent company of Pfizer Pharmaceuticals LLC.

7. Plaintiff Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V. is a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law, having its registered seat in Rotterdam, the Netherlands, having its business address at Rivium Westlaan 142, 2909 LD, Capelle aan den IJssel, the Netherlands, and registered with the Dutch Trade Register under number 60558814. Pfizer Inc. is the ultimate parent company of Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

8. On information and belief, defendant Prinston Pharmaceutical Inc. is a company organized and existing under the laws of Delaware, having its principal place of business at 2002 Eastpark Blvd., Cranbury, NJ 08512.

JURISDICTION AND VENUE

9. This action arises under the patent laws of the United States, Title 35, United States Code. The Court has subject matter jurisdiction over this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Venue is proper in this judicial district pursuant to the provision of 28 U.S.C. § 1400(b).

11. This Court has personal jurisdiction over Prinston.

12. This Court has personal jurisdiction over Prinston by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in Delaware. In particular, this suit arises out of Prinston Pharmaceutical Inc.'s filing of ANDA No. 209923 seeking FDA approval to sell 5 mg tofacitinib tablets ("Prinston Generic Tablets") prior to the expiration of the '027 and '023 patents, throughout the United States, including in Delaware.

13. This Court has personal jurisdiction over Prinston Pharmaceutical Inc. because it is a Delaware entity.

14. On information and belief, if ANDA No. 209923 is approved, Prinston Generic Tablets will, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, dispensed by pharmacies located in Delaware, and/or used by patients in Delaware.

15. Prinston's infringing activities with respect to its filing of ANDA No. 209923 and its intent to commercialize and sell Prinston Generic Tablets has led and/or will lead to

foreseeable harm and injury to Plaintiffs, including Pfizer Inc., which is incorporated in Delaware.

16. On information and belief, Prinston maintains substantial, systematic, and continuous and systemic contacts throughout the United States, including with Delaware. Prinston's website states that it "meets market needs through innovation" by "rapidly bringing cost-effective quality products to the US market." (http://www.prinstonpharm.com/about_us.html (last accessed June 14, 2018)). Prinston's website indicates that it distributes seventeen generic products in the United States. (*See* http://www.prinstonpharm.com/Products_List.html (last accessed June 14, 2018)).

17. Prinston has previously availed itself of the United States District Court for the District of Delaware by consenting to the court's jurisdiction and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Astellas Pharma Inc. et al. v. Prinston Pharm. Inc.*, No. 1:16-cv-00943-SLR (D. Del.) (D.I. 16); *AstraZeneca LP et al. v. Prinston Pharm. Inc.*, No. 1:15-cv-01057-RGA (D. Del.) (D.I. 12); *Bayer Intell. Prop. GMBH et al. v. Aurobindo Pharma Ltd. et al.*, No. 1:15-cv-00902-RGA (D. Del.) (D.I. 30); *Teijin Ltd. et al. v. Prinston Pharm. Inc.*, No. 1:14-cv-00854-SLR (D. Del.) (D.I. 8).

BACKGROUND

Xeljanz®

18. Tofacitinib citrate is an inhibitor of Janus kinases ("JAKs") and is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate.

19. The active ingredient in Xeljanz® is tofacitinib citrate. Xeljanz® contains tofacitinib citrate in an amount equivalent to 5 mg of tofacitinib base in a tablet formulated for twice-daily administration.

20. The FDA-approved Prescribing Information for Xeljanz® states that tofacitinib citrate has the following chemical name: (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo [2,3-d] pyrimidin-4-ylamino)-ß-oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1).

Orange Book Listing for Xeljanz®

21. PF PRISM C.V. holds approved New Drug Application ("NDA") No. 203214 for EQ 5 mg base tofacitinib citrate tablets, which Pfizer sells under the registered name Xeljanz®.

22. Pursuant to 21 U.S.C. § 355(b)(1) and the regulations the FDA has promulgated pursuant thereto, the '027 and '023 patents are listed in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") for the Xeljanz® NDA.

23. The Orange Book lists the expiration date for the '027 patent as March 25, 2023 and the '023 patent as May 23, 2022.

24. The Orange Book also lists four additional patents for Xeljanz® that are not at issue: U.S. Patent Nos. 6,956,041 (expiring December 8, 2020); 7,091,208 (expiring December 8, 2020); 7,265,221 (expiring December 8, 2020); RE41,783 (expiring December 8, 2020). On December 14, 2016, the United States Patent and Trademark Office ("USPTO") issued a Notice of Final Determination extending the expiration date of the RE'783 patent to December 8, 2025.

The '027 Patent

25. On November 15, 2005, the USPTO issued the '027 patent, titled "Crystalline 3-{4-methyl-3-[methyl-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-amino]-piperidin-1-yl}-3-oxo-propionitrile citrate." The '027 patent is duly and legally assigned to Pfizer Inc. A copy of the '027 patent is attached hereto as Exhibit A.

26. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’027 patent.

27. C.P. Pharmaceuticals International C.V. conveyed rights under the ’027 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V, and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

28. Pursuant to a Deed of Conversion and Amendment to Articles of Association dated December 30, 2017, Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

The ’023 Patent

29. On November 27, 2007, the USPTO issued the ’023 patent, titled “Chiral Salt Resolution.” The ’023 patent is duly and legally assigned to Pfizer Inc. A copy of the ’023 patent is attached hereto as Exhibit B.

30. C.P. Pharmaceuticals International C.V. is the exclusive licensee of the ’023 patent.

31. C.P. Pharmaceuticals International C.V. conveyed rights under the ’023 patent to Pfizer Pharmaceuticals LLC, PF PRISM C.V, and Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A.

32. Pursuant to a Deed of Conversion and Amendment to Articles of Association dated December 30, 2017, Pfizer PFE Ireland Pharmaceuticals Holding 1 Coöperatief U.A. changed its name to Pfizer PFE Ireland Pharmaceuticals Holding 1 B.V.

Prinston’s ANDA

33. By letter dated January 16, 2017 (the “Prinston Notice Letter”) and received by Pfizer on January 17, 2017, Prinston notified Pfizer that it had filed ANDA No. 209923 with the

FDA, seeking approval under the Federal Food, Drug and Cosmetic Act ("FDCA") to market and sell Prinston Generic Tablets prior to the expiration of the '027 and '023 patents.

34. The Prinston Notice Letter asserts that ANDA No. 209923 contains a "Paragraph IV" certification under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) alleging that each of the '027 and '023 patents "are invalid or unenforceable" and "will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of" Prinston Generic Tablets.

35. The Prinston Notice Letter indicates that Prinston Generic Tablets will contain tofacitinib citrate as the active ingredient.

36. The Prinston Notice Letter states that ANDA No. 209923 seeks "to obtain approval to engage in the commercial manufacture, use or sale of" Prinston Generic Tablets prior to the expiration of the '027 and '023 patents.

37. Attached to the Prinston Notice Letter was Prinston's Detailed Statement ("Prinston's Detailed Statement") asserting the purported factual and legal bases for Prinston's contention that the '027 and '023 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, and/or sale of Prinston Generic Tablets.

38. Prinston's Detailed Statement alleges that all claims of the '027 and '023 patents are invalid. Other than with respect to claim 5 of the '027 patent, Prinston's Detailed Statement does not contain a noninfringement argument with respect to any claim of the '027 and '023 patents, other than that all claims are invalid.

39. On information and belief, upon approval of ANDA No. 209923, Prinston will distribute Prinston Generic Tablets throughout the United States.

COUNT I
(Infringement of the ’027 Patent by Prinston Generic Tablets)

40. The allegations of paragraphs 1-39 above are repeated and re-alleged as if set forth fully herein.

41. Pursuant to 35 U.S.C. § 271(e)(2)(A), Prinston Pharmaceutical Inc.’s filing of ANDA No. 209923 seeking approval to market Prinston Generic Tablets is an act of infringement of one or more claims of the ’027 patent entitling Pfizer to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209923 be a date which is not earlier than the expiration date of the ’027 patent.

42. Prinston had knowledge of the ’027 patent when it submitted ANDA No. 209923 to the FDA.

43. On information and belief, upon FDA approval, Prinston intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Prinston Generic Tablets and will thereby infringe at least claim 1 of the ’027 patent.

44. The foregoing actions by Prinston constitute and/or would constitute infringement of at least claim 1 of the ’027 patent.

45. Pfizer will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’027 patent. Pfizer has no adequate remedy at law.

COUNT II
(Infringement of the ’023 Patent by Prinston Generic Tablets)

46. The allegations of paragraphs 1-45 above are repeated and re-alleged as if set forth fully herein.

47. Pursuant to 35 U.S.C. § 271(e)(2)(A), Prinston Pharmaceutical Inc.’s filing of ANDA No. 209923 seeking approval to market Prinston Generic Tablets is an act of infringement of claim 1 of the ’023 patent entitling Pfizer to the relief provided by 35 U.S.C. §

271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 209923 be a date which is not earlier than the expiration date of the ’023 patent.

48. Prinston had knowledge of the ’023 patent when it submitted ANDA No. 209923 to the FDA.

49. On information and belief, upon FDA approval, Prinston intends to engage in the manufacture, use, offer for sale, sale, and/or importation of Prinston Generic Tablets and will thereby infringe claim 1 of the ’023 patent.

50. The foregoing actions by Prinston constitute and/or would constitute infringement of claim 1 of the ’023 patent.

51. Pfizer will be substantially and irreparably harmed if Prinston is not enjoined from infringing the ’023 patent. Pfizer has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Pfizer requests the following relief:

A. A judgment that Prinston Pharmaceutical Inc.’s submission of ANDA No. 209923 was an act of infringement and that Prinston’s making, using, offering to sell, selling or importing Prinston Generic Tablets prior to the expiration of the ’027 and ’023 patents will infringe each of those patents;

B. A judgment that the effective date of any FDA approval for Prinston to make, use offer for sale, sell, market, distribute, or import the Prinston Generic Tablets be no earlier than the dates on which the ’027 and ’023 patents expire, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

C. A permanent injunction enjoining Prinston, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from making using, selling, offering for sale, marketing, distributing, or importing Prinston Generic

Tablets, and from inducing or contributing to any of the foregoing, prior to the expiration of the '027 and '023 patents, or any later expiration of exclusivity to which Pfizer is or becomes entitled;

D. A judgment that this case is an exceptional case under 35 U.S.C. § 285, entitling Pfizer to an award of its reasonable attorneys' fees for bringing and prosecuting this action;

E. An award of Pfizer's costs and expenses in this action; and

F. Such further and additional relief as this Court deems just and proper.

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